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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/686,490	10/15/2003	Boris Bosch	CH-7886/LeA 35,991	8792
34947	7590	05/02/2006	EXAMINER	
LANXESS CORPORATION 111 RIDC PARK WEST DRIVE PITTSBURGH, PA 15275-1112				SAIDHA, TEKCHAND
		ART UNIT		PAPER NUMBER
		1652		

DATE MAILED: 05/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/686,490	BOSCH ET AL.
	Examiner	Art Unit
	Tekchand Saidha	1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 31 March 2006.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-26 is/are pending in the application.
4a) Of the above claim(s) 1-12, 24 and 26 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 13-23 and 25 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 8/27/04.

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ .

5) Notice of Informal Patent Application (PTO-152)

6) Other: ____ .

DETAILED ACTION

1.

Election

Applicant's election with traverse of Group IV (claims 13-23 & 25) in is acknowledged. The traversal is on the grounds that the search classification for each of the invention group substantially overlap. For example, the Examiner indicates that a search for invention IV and V would be class 436, subclass 145. Applicants respectfully submit that such search can be concurrently performed and that the Examiner will not be seriously burdened by searching and considering the inventions as described in all the presently filed claims. According, Applicants respectfully request withdrawal of the Restriction requirement from Invention I-V.

This is not found persuasive because depending upon the restricted group (I or II) being examined, additional classes/subclasses have to be searched. For example, Group I claims, drawn to gene encoding a anti-Kazlauskas lipase, vector, host cell and a method of making the protein, will involve searching for additional class 536 & subclass 23.2 for DNA encoding the enzyme; vector - class 435, subclass 320.1 and host cell - class 435, subclass 252.3; and Group II claims, drawn to a anti-Kazlauskas lipase, will involve searching for additional class 435 & subclass 198 for the anti-Kazlauskas lipase. Further searching will involve structural and sequence data bases searching for the anti-Kazlauskas lipase and the DNA encoding the same.

Similarly, the Inventions of Groups IV and V, even though classified in the same class and subclass, correspond to methods of making compounds of different formulae and have different method steps, will involve different searches for the compounds.

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Therefore, while Groups I and II are classified in the same class/subclass (435/198); and Groups IV and V are similarly classified in the same class/subclass (435/145), the searches are not co-extensive and therefore searching for one group does not always gather art for the other group.

This additional searching as explained above would therefore involve undue burden to the Examiner. The requirement is still deemed proper and is therefore made FINAL.

2. **Claims withdrawn :**

Claims 1-12, 24 & 26 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

3. **Specification**

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

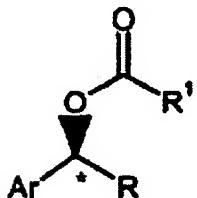
4. **Priority**

Acknowledgment is made of applicants' claim for priority based on an application filed in Germany on 10/16/2002.

5. **Written Description**

Claims 13-23 & 25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These claims are directed to a method of preparing a compounds of

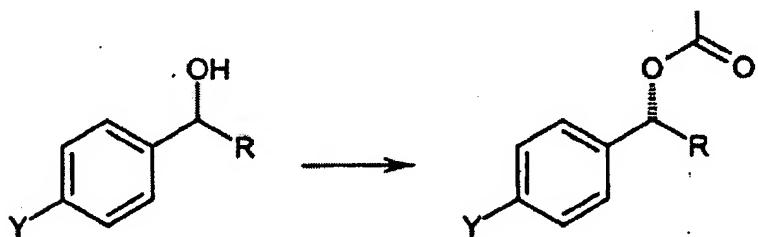


the formula I,

using any anti-Kazlauskas lipase i.e. a lipase that does not obey the Kazlauskas rule (see Kazlauskas et al. *J. Org. chem.* 1991, 56: 2656-2665; specification, page 6, lines 5-7), i.e. an anti-Kazlauskas lipase from any source, the claimed genus, and to which no associated structure is apparent.

The specification does not contain any disclosure or description of the structure and function of all the anti-Kazlauskas lipases from any source. Further, the specification as filed does not show that the single disclosed lipase would catalyze variously modified compounds of formula III, IV, V, VI & VII in order to produce the compound of Formula I.

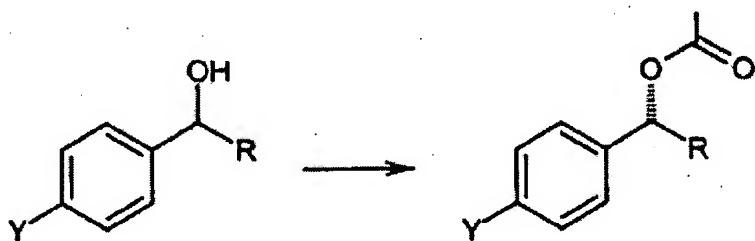
The instant specification disclose a single lipase species of SEQ ID NO: 2, and the catalysis of a single reaction species of acylation by the anti-Kazlauskas lipase of SEQ ID NO: 2 (see page 27). The reaction catalyzed by the lipase is shown by the equation -



It would be highly improbable to assume based upon the single example of the enzyme of SEQ ID NO: 2 and the single substrate, that a variety of lipases would effectively utilize a range of variously modified substrate compounds of formula III, IV, V, VI & VII in the method claimed, and further using in the preparation of medicaments or agrochemicals. The genus of lipases and/or substrate compounds that comprise these molecules (i.e., lipases/compounds) is a large variable genus undescribed and encompassed within the scope of these claims. The single species exemplified is not representative of the genus claimed and is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

6. **Enablement Rejection**

Claims 13-23 & 25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of preparing a compound, using anti-Kazlauskas lipase of SEQ ID NO: 2, and represented by the following equation X:



does not reasonably provide enablement for making compounds of the formula I, using anti-Kazlauskas lipases from any source and

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further utilizing a range of variously modified substrate/catalyst compounds of formula III, IV, V, VI & VII. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The scope of the claims does not commensurate with the enablement provided by the disclosure with regard to the extremely large number of anti-Kazlauskas lipases and substrate compounds broadly encompassed by the claims. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of obtaining a diverse range of anti-Kazlauskas lipases from any source to be effective in catalyzing a range of variously modified substrates to produce the desired activity or compound is remote; and requires sufficient examples, knowledge in the prior art and guidance with regard to the occurrence of such lipases and substrate specificities, in order for the method to be reasonably effective.

However, in this case the disclosure is limited to the anti-Kazlauskas lipase having the amino acid sequence of SEQ ID NO: 2 and the single acylation reaction represented by the equation given above. It would be highly unpredictable to extrapolate the guidance of a single reaction system to include a method of preparing a range of variously modified compounds and using anti-Kazlauskas lipases from any source; and further use in the preparation of medicaments or agrochemicals. Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the

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scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of the method of preparing various modified compounds of Formula I using anti-Kazlauskas lipases from any source is highly unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

7. **Claim Rejections - 35 USC § 112** (second paragraph)

Claims 13-23 & 25 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13, last line, recites the phrase 'biological activity'. The claim is unclear because 'biological activity' may include 'immunological activity', and immunological activity cannot catalyze the reaction. Amending the claim to recite 'enzymatic activity', will overcome this rejection.

Claims 14-23 & 25 are included in the rejection for failing to correct the defect present in the base claim(s).

8. No claim is allowed.

9. Claims drawn to 'A method of preparing a compound as given in the equation X (as stated above in paragraph 6) using anti-Kazlauskas lipase of SEQ ID NO: 2' would be in a better condition for allowance.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tekchand Saidha whose telephone number is (571) 272 0940. The examiner can normally be reached on 8.30 am - 5.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy

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can be reached on (571) 272 0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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